A 04

8EHQ-0992-12826

Chemicals Division

CIBA-GEIGY Corporation
P. O. Box 18300
Greensboro, North Carolina 27419-8300
Telephone 919 632 6000

"Contains NO CBI"

CIBA-GEIGY

SEE DOCUMENT RECEIPT OF...

92 SEP -1 PM 1:41

8EHQ-92-12826
INIT 09/01/92

88920010891

August 28, 1992

Document Processing Center (TS-790)
Office of Toxic Substances
Environmental Protection Agency
401 M. Street, SW
Washington, DC 20460

Attention: Section 8(e) Coordinator (CAP Agreement)

RE: 8E CAP - 0024

Dear Section 8(e) Coordinator:

Enclosed are the original and two copies of a study CIBA-GEIGY Corporation is submitting pursuant to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement number 8E CAP-0024. We are submitting the following information, as required by the CAP Agreement:

Company Name: CIBA-GEIGY Corporation
444 Saw Mill River Road
Ardsley, New York 10502-2699

Attention: Mr. Anthony Di Battista
Manager, Regulatory Affairs & Toxic Substances Compliance
Telephone (914) 479-2776

Tested Chemical:

Thiols, C8-20, gamma-omega -perfluoro, telomers with acrylamide; identified as Lodyne K81'84

CAS No.: 70969-47-0

Report Title: Single Dose Oral Toxicity in Rats/Acute Oral LD 50 in Rats (Project No. MB 85-7641 A, dated 4/17/85)

Summary:

The test material was administered orally to ten rats (5/sex) at a dose of 5 gm/kg which resulted in mortality in 7/10. Physical signs noted in survivors were piloerection, alopecia and brown staining of the anogenital area, lethargy, ptosis, chromodacryorrhea, chromorhinorrhea, and ataxia. Based on the observation of ataxia in two surviving males observed over 2 to

3 days, followed by lethargy, it is concluded that the test material exhibits neurotoxicity potential at high oral doses.

Category: Unit II.B.2.b

Prior Reporting: Not Applicable

Please call the undersigned at (919) 632-7237 if you have any questions about this submittal.

Very Truly Yours,

Keith A. Hostetler

Keith A. Hostetler, Ph.D., DABT
Manager, Hazard Assessment
Chemicals Division

Enclosures
(2 copies of this letter)
(3 copies of the study)

cc: A. Di Battista

Codeine 6/8/84

I.D. # 12562

MB Research Laboratories, Inc.

steinsburg and wentz roads
post office box 178
spinnerstown, pennsylvania 18968
215-536-4110

PROJECT NUMBER: MB 85-7641 A
TEST ARTICLE : MA-126, Tox #85-015
SPONSOR : CIBA-GEIGY CORPORATION
TITLE : SINGLE DOSE ORAL TOXICITY IN RATS/ACUTE ORAL LD 50 IN RATS
PROTOCOL # : 31-02 R/A

ABSTRACT

Method Synopsis - Five healthy male and five healthy female albino rats were dosed orally with MA-126 at 5.0 g/kg of body weight. The rats were observed 1, 2 and 4 hours after dosing and daily for 14 days for mortality, toxicity and pharmacological effects. Body weights were recorded pretest, at death and at termination in the survivors. All animals were examined for gross pathology. Although seven animals died at the 5.0 g/kg dose level, a multi-dose LD 50 was not performed per client request.

Summary - Three of ten animals survived the 5.0 g/kg oral dose.

Five females and two males died during the study. Predeath physical signs were wetness of the nose/mouth area, lethargy, ptosis, piloerection, brown staining of the anogenital area, ataxia, wetness of the anogenital area, chromodacryorrhea, chromorhinorrhea, dyspnea, few feces, redness of the anogenital area and tachypnea. Necropsy of the deaths revealed abnormalities of the gastrointestinal tract, brown and yellow staining of the anogenital area and red and brown staining of the nose/mouth area.

Physical signs noted in survivors were piloerection, brown staining of the anogenital area, lethary, alopecia of the anogential area, ptosis, chromodacryorrhea, chromorhinorrhea, wetness of the nose/mouth area, ataxia, few feces and wetness of the anogenital area.

Body weight increases and necropsy results of survivors were normal.

Conclusion - The LD 50 is less than 5.0 g/kg of body weight.

QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit reviewed various aspects of the raw data and final report on the following dates:

April 9, 1985
April 16, 1985

Bonnie W. Cerven 4/17/85
Bonnie W. Cerven
Quality Assurance

Respectfully submitted,

Oscar M. Moreno 4/16/85
Oscar M. Moreno, Ph.D.

Daniel R. Cerven 16 Apr 85
Daniel R. Cerven, Study Director

Elizabeth J. Altenbach 4/15/85
Elizabeth J. Altenbach, Archivist
Submitted: 4/17/85

TITLE OF REPORT

SINGLE DOSE ORAL TOXICITY IN RATS/ACUTE ORAL LD 50 IN RATS

PROTOCOL NUMBER

31-02 R/A

OBJECTIVE

To determine the potential for toxicity of the test article when administered orally. Initially a 5.0 g/kg dose was administered to five male and five female rats. If two or more of the same sex or three of either sex died and the deaths were attributed to test article administration, then an LD 50 was conducted.

TEST ARTICLE

Source and Date Received	:	CIBA-GEIGY CORPORATION 3/06/85
Label	:	MA-126, Tox #85-015
Storage	:	The test article was stored at ambient room temperature and humidity.
Description of Test Article	:	Clear Viscous Liquid
Specific Gravity	:	1.25
Sample Preparation	:	Used as received

TEST ANIMALS

Five male and five female Wistar Albino rats/group were selected for this test from a larger group which had been quarantined at least one week. The animals were received from Ace Animals on 3/12/85.

The pretest body weight range was 204-236 g for males and 196-223 g for females.

Animals were identified by cage notation and indelible body marks.

The animals were housed 5/cage in suspended wire mesh cages. Bedding was placed beneath the cages. Fresh Purina Rat Chow (Diet #5012) was freely available except for 16-20 hours prior to dosing. Water was freely available at all times.

The animal room, reserved exclusively for rats on acute tests, was temperature and humidity controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.

TEST DATES

Dose g/kg	Date Started	Date Ended
5.0	3/20/85	4/03/85

EXPERIMENTAL DESIGN

The test article was administered orally, one time, by syringe and dosing needle at a dose level of 5.0 g/kg. *If two or more of one sex or three of either sex died, a four dose level screen in two rats was run to determine four dose levels for the LD 50.* For liquid materials, the dose was based on the sample weight as calculated from the specific gravity. For solids and other semi-solids, the test article was mixed with a vehicle to make dosing by gavage possible. The dose was based on the dry weight of the test article. The dose schedule follows:

GROUP	DOSE g/kg
MA-126	5.0

TYPE AND FREQUENCY OF OBSERVATIONS

In Vivo : Animals were observed 1, 2 and 4 hours post dosing and once daily thereafter for 14 days for mortality, toxicity and pharmacological effects.

Body weights were recorded pretest and at termination.

Post Mortem : All animals were examined for gross pathology.

ANALYSIS OF DATA

If fewer than three rats died, the LD 50 was estimated to be greater than 5.0 g/kg. If additional doses were given, the LD 50 and 95% Confidence were calculated by the method of Litchfield, J.T. Jr., & F. Wilcoxon JPET 96:99, 1949 or Horn H.J. Biometrics 12:311, 1956.

The test article was; 1) not toxic if the LD 50 was greater than 5.0 g/kg; 2) toxic if the LD 50 was less than 5.0 g/kg and greater than 50 mg/kg; 3) highly toxic if the LD 50 was less than 50 mg/kg.

 SEE REVISION OF THE PROTOCOL

RETENTION OF DATA

The raw data is filed at MB Research by MB project number. The final report is filed at MB Research by sponsor name and MB project number.

The test article will be retained for six months from date of this report.

REVISION OF THE PROTOCOL

A multi-dose LD 50 was not performed, as per client request.

RESULTS

1. LD 50:

The LD 50 is less than 5.0 g/kg of body weight.

2. MORTALITY:

Dose Level g/kg	# Treated M/F	# Dead M/F	Day of Death (M/F) 0	1	4	6
5.0	5/5	2/5	0/1	0/4	1/0	1/0

3. BODY WEIGHTS AND DOSE VOLUME:

An. # & Sex	Dose Volume cc	Day 0 g	Day 14 g
1-M	0.84	210	DEAD DAY 6*
2-M	0.94	236	342
3-M	0.87	217	DEAD DAY 4 (158 g)
4-M	0.82	204	291
5-M	0.88	221	316
MEAN		217.6	316.3
S.D.		12.2	25.5
6-F	0.87	218	DEAD DAY 1 (205 g)
7-F	0.89	223	DEAD DAY 0
8-F	0.84	210	DEAD DAY 1 (204 g)
9-F	0.88	220	DEAD DAY 1 (211 g)
10-F	0.78	196	DEAD DAY 1 (188 g)
MEAN		213.4	----
S.D.		10.9	----

*animal was cannibalized; therefore, terminal body weight was not recorded

@ 5.0 g/kg

TOXICITY

MB RESEARCH LABS
PROJECT: MB 85-7641 A

AN.= & SEX	HOUR 1	HOUR 2	HOUR 4	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10	DAY 11	DAY 12	DAY 13	DAY 14
1-M	1	1		BQEF MJ	QBEFJ S2X	QMEFB12	BF2	FBNJ2	Z(cannibalized)----------								
2-M	1	1	BQ	SJBQF	SJBQF E24X	FB2	FB2	FB2	F26	F26	F				F	F	F
3-M	1	BQE1	BQEF1	SBQEF	SJBQF E24X	FBSJ2	Z----------										
4-M	1	12	2	SBQEFJ	SJBQE F24X	FSB2	FB2	FBJ2	FJ26	F26	FQ6	FQ6	F6	F6	F6	F6	F
5-M	1	1		SBQF	SJBQE F24X	FSEB2	BF2	BF2	F2	F2	F	F6	F6	F6	F6	F6	F
6-F	E1	QB14	QB14	Z----------													
7-F	1	Q1	BQ14Z----------														
8-F	1	12	BQ124	Z----------													
9-F	1	B12	BFQ24	Z----------													
10-F	1	13	BQF134	Z----------													

AT ALL TIMES NOT MENTIONED, ALL ANIMALS APPEARED NORMAL.

CODE: B = lethargy
E = ataxia
F = piloerection
J = chromodacryorrhea
M = dyspnea
Q = ptosis
S = chromorhinorrhea
Z = dead
X = few feces

1 = nose/mouth wet
2 = anogenital area stained brown
3 = anogenital area stained red
4 = anogenital area wet
6 = alopecia at anogenital area

NECROPSY OBSERVATIONS

@ 5.0 g/kg:	1-M D	2-M S	3-M D	4-M S	5-M S	6-F D	7-F D	8-F D	9-F D	10-F D
Normal	X									
Cannibalized		X		X	X					
Nose/mouth stained red										
Nose/mouth stained brown										
Anogenital area stained brown			1					2		
Anogenital area stained yellow			3			1	1		1	1
Stomach, red						3	1	2	2	2
Stomach distended with dark brown fluid						3	2	3	3	3
Stomach distended with gas						3	3	3	3	3
Intestines, red			2							
Intestines distended with mucus						3	3	3	3	3
Intestines distended by clear fluid			2							
Intestines distended by dark mucus						3	3	3	2	1
			X							

CODE: D = death
S = sacrifice
1 = slight or scattered
2 = moderate or few
3 = pronounced or many
X = observed

MB RESEARCH LABORATORIES

STUDY TITLE: SINGLE DOSE ORAL TOXICITY/LD 50 IN RATS

PROTOCOL NO: 31-02 L/F

SAMPLE: MA-126, Tox #85-015

DT. REC'D:	LOC:	SAMPLE DESC:	PH:	SPG:	PROJECT NO:
3/6/85	B	Coral Rose Liq	/	1.25	85-7641.A

UAR/ DT:	AMT. USED:	DOSE AMT.	SAMPLE PREPARATION(S) - IF REQUIRED	BY:	DT:	TM:
3/20	15 mL					

SPONSOR: CIBA

STUDY DIR:

TEST START: 3/20/85

TEST END: 3/[illegible]/85

DOSING NEEDLE:

PROTOCOL SYNOPSIS: USE 5M & 5F W/A RATS/Grp. HOUSE 5/sex/Cg. PRETEST BODY WT. RANGE: Males 200-250; Females 180-230g. DOSE @ 5.0 g/kg. OBSERVE 1, 2 & 4 hrs postdose & x day for 14 days. BODY WTS Pre, death & @ term in survivors. NECROPSY ALL.

LD 50: If 2 or more ans of same sex die, or if 3 ans of either sex die @ 5.0 g/kg, DOSE 4 add'l grps based on results of screen. If 5.0 g/kg level is nec. for calc. of LD 50, it will be repeated. DOSE ALL LD 50 LEVELS SIMULTANEOUSLY.

Screen: DOSE 4 grps of 2 rats/grp. One level must be 0.5 g/kg. NO NECROPSY.

COMMENTS:

LD 50: < 5 g/kg

FOOTNOTES:

1=Nose/mouth wet brown 3/20/85

2: AGA brown 3/20/85

3: AGA wet 3/20/85

4: AGA wet 3/20/85

6: [illegible]

A = NORMAL
B = LETHARGY
C = FLACCID
D = DIARRHEA
E = ATAXIA
F = PILOERECTION
G = PROSTRATE
H = COMA
I = CONVULSION
J = CHROMODACRYORRHEA
K = NEGATIVE RIGHTING REFLEX
M = DYSPNEA
N = TACHYPNEA
O = TREMOR
P = SPASM
Q = PTOSIS
R = ALOPECIA
S = CHROMORHINORRHEA
V = ABDOMEN BLOATED
W = APPEARS EMACIATED
X = FEW FECES
Y = YELLOW NASAL DISCHARGE
Z = DEAD
RT = RECORDING ERROR

OMM=D. MORENO JS=J. SMARTSCHAN DRCR=D. CERVEN DMCR=D. CERVEN BA=B. ALTENBACH DH=D. HALL
MTM=T. MORENO SEW=S. Weatherby AR=A. BLANCO BY=B. YENSER (D/RS)

QUALITY ASSURANCE:

	DATE	INIT
STY. INSPECTED :		
RAW DATA AUDITED:	4/17/85	DC
FIN'L REPT ADT'D:	4/16/85	[illegible]

MBR

SAMPLE: MA 126	SPONSOR: CIBA	STUDY TITLE: SDOT/LD 50	PROJECT #: 85-7641 A	PROTOCOL #: 31-02

DOSE: 5C /KG BY: [illegible] DT: 3/20 TM: 9:30
VIA: GAVAGE: ✓ DIET:

DOSE VOLUME: 4.00 ML/KG | SUPP/REC'D: A 3/12 | RM/RK: 8/36 (*) | SEXED BY: JS | FASTED: TM: 4:00 BY: [illegible]

(*) / = see cage trans. form

AN. # SEX L.D.	VOL CC	BODY WT - G 0	BODY WT - G 14	DAY 0 1 HR	DAY 0 2 HR	DAY 0 4 HR	OBSERVATIONS 1	2	3	4	5	6	7	8	9	10	11	12	13	14
# M H	0.84	210		1	1	A	BAEF MJ	2AEF FS SX	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]						
# M B	0.84	236	342	1	1	BQ	SSB QF	SSBQF E2 SX	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	F	P	A	A	F	[illegible]	F
# M TB	0.87	217		1	1BQ E	1BQ [illegible]	SBQ EF	4255 BQF SX	[illegible]	[illegible]										
# M TE	0.87	204	291	1	12	2	SBQ EFS	2455 2AEF SX	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	F	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	F
# M E	0.85	221	316	1	1	A	SBQ F	2455 BAEF X	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	F	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	F
# F RS	0.87	218		1E	1QB 4	1QB ↓	Z (208)													
# F LS	0.87	223		1	1Q	1QB 4/2	3:30													
# F RH	0.84	210		1	12	12B Q4	E (204)													
# F LH	0.85	220		1	12B	42B 1Q	Z (211)													
# F TO	0.85	196		1	13	143 BQF	Z (188)													
DATE:	3/20	→	3/21	3/20	→		3/21	3/22	[illegible]	[illegible]	3/[illegible]	[illegible]	[illegible]	[illegible]	3/[illegible]	3/30	3/31	[illegible]	[illegible]	4/3
TIME:	9:30	→	[illegible]	10:30	1:30	[illegible]	9:29	9:28	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	10:23	10:31	[illegible]	[illegible]	[illegible]
INIT:	[illegible]	→	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	MJ	MJ	[illegible]	[illegible]	[illegible]
VERF:	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

MB PROJ. #: _____ | NECROPSY OBSERVATIONS-RAT(S) MB PROTOCOL

TEST ARTICLE: _____ SACRIFICE AGENT: _____

DATE OF DEATH						3/21	3/21	3/21		
TEST DAY						1	1	1		
SACRIFICE(S)//DEATH(D)						D	D	D		
DOSE G/KG										
ANIMAL NUMBER/SEX										
NORMAL										
CANNIBALIZED										
Nose/mouth stained red								2		
Nose/mouth stained brown			1			1	1		1	1
AGA stained red										
AGA stained brown			3							
AGA yellow						3	1	2	2	2
Lungs: Congestion										
Lungs: Hemorrhage										
Heart dilated										
Pericarditis										
Pleural cav.-excess fluid										
Liver Nodule(s)										
Liver abscess(es										
Kidney(s) hydronephrotic										
Stomach red						3	2	3	3	3
Stomach distended w/dark brown fluid						3	3	3	3	3
" " w/ gas			2							
Intestines red						3	3	3	3	3
Intestines distended-mucus			2							
Intestines distended by clear fluid						3	3	3	2	1
" " " dark gas										
Peritoneal cav-excess fluid										
DATE NECROPSIED:						3/21	3/21	3/21		
NECROPSIED BY :										
VERIFIED BY :										

1=slight or scattered 2=moderate or few 3=pronounced or many ✓ = observed

OMM=O. MORENO JS =J. SMARTSCHAN DRC=D. CERVEN B =B. CERVEN BA = B ALTENBACH BY =B. YEISER
MTMMT. MORENO SEW=M. WEATHERBY AR =A. BLASKO DR =D. Hill (11/81)

B 01

06/11/92 COLORS COMPONENT LANGUAGE INFO GCLFN960
Action Code: (A,C,D)
Comp-Num: 02584 Lang Code: ENG
Cas-Num: 70969-47-0

Oshapel Desc: NOT ESTABLISHED Iarc Desc: NOT LISTED
Acgih-Tlv Desc: NOT ESTABLISHED Ntp Desc: NOT LISTED
TSCA Status: T (T=TSCA,R=R&D,E=Pesticide,F=FDA,P=PMN,N=unk,I=Impure,D=Descr)
Idl: CEPA: D (D=DSL, R=NSN,L=NDSL,T=Transitional list, N=not on list)

Type Ssd Translation Page: 01
CM FLOUOROCHEMICAL NONIONIC SURFACTANT
CN Thiols, C8-20, .gamma.-.omega.-perfluoro, telomers with acrylamide
CP LODYNE K8184 A.I.

Next Selection:

B 02

PERCENTAGE -> 100.15

06/12/92 COLORS COMPONENT SCROLL MAINTENANCE Page 01 GCLFN963

Language ENG

Product 309005100 001 LODYNE K8184 30%

Component

ACTIVE COLORANT CODE

TSCA Status T=TSCA, R=R&D

E=Pesticide, F=FDA, P=PMN, I=Impur, D=Descrp

S	Nbr	Description	Cas No	TS	Percent	O	Sh	Sn	Rn
_	02508	BUTYL CARBITOL	112-34-5	T	32.00	B	N	Y	N
_	01828	WATER	7732-18-5	T	30.00	N	N	Y	N
_	02584	LODYNE K8184 A.I.	70969-47-0	T	30.00	N	N	Y	N
_	02509	N-PROPANOL	71-23-8	T	8.00	O	Y	N	N
_	02510	ACRYLAMIDE	79-06-1	T <	0.10	N	N	N	N
_	00003	ACETIC ACID	64-19-7	T	0.05	N	N	N	N

Next Selection: History Info, Create 06 12 92 Revise 03 17 92 by FAIRFRI963